

31. (Amended) A method of modifying a cornea having a main optical axis and an external surface, comprising the steps of

aiming and firing an ultrashort pulse laser at the cornea, which separates an internal area of the cornea adjacent the external surface into first and second internal surfaces to form an internal pocket, the first internal surface facing in a posterior direction of the cornea and the second internal surface facing in an anterior direction of the cornea,

forming an opening from the surface of cornea to the internal pocket,

introducing an ocular gel through the opening and into the internal pocket and in between the first and second internal surfaces of the internal pocket,

placing a contact lens having a predetermined curvature on the surface of the cornea to shape the ocular gel, and

irradiating the ocular gel so that the ocular gel solidifies.

REMARKS

In the October 15, 2002 Office Action, of pending claims 1-35, claims 24-31 are rejected under 35 U.S.C. §112, second paragraph and claims 1-15, 17-35 are rejected under 35 U.S.C. §103(a).

Applicant will assume for purposes of this response that claim 16 is also rejected as being obvious in view of the prior art. However, Applicant notes that claim 16 has been canceled and the subject matter thereof has been included in claim 1.

By this Amendment, claims 16 and 22 are canceled and claims 1, 20 and 24-31 are amended, leaving claims 1-15 and 17-21 and 23-35 pending with claims 1, 20, 24 and 31 being independent.

Reconsideration and allowance of the above-identified application is respectfully requested.

Rejections Under 35 U.S.C. §112, second paragraph

Claims 24-31 are rejected under 35 U.S.C. §112, second paragraph as being indefinite. Specifically, the Action alleges that claims 24-30 are incomplete, as a system is recited in the preamble, yet no structural cooperation or linkage between the separate elements is claimed.

As noted above, claims 24-30 have been amended to include the word “kit”, and therefore it is believed that they now overcome the §112, second paragraph rejection. Applicant further notes that this amendment is not made to limit the scope of the claims and believes that the word “system”, as used in the claims of the application, does not in itself render the above claims indefinite. However, to expedite prosecution, Applicant has amended the above claims, to recite the more commonly used word “kit”.

With regard to claim 31, the Action notes that the meaning of the term “he ocular material” is unclear. As noted above, this claims is amended to overcome this rejection.

Rejections Under 35 U.S.C. §103(a)

Claims 1-4, 7-13 and 17-19 stand rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 4,907,586 to Bille et al. in view of over U.S. Patent No. 5,090,955 to Simon.

Independent Claim 1

The combination of the Bille et al. patent and the Simon patent does not disclose, teach or suggest all the elements of amended independent claim 1. Specifically, this combination does not disclose, teach or suggest placing a contact lens having a predetermined curvature on the external surface of the cornea to shape ocular material.

Applicant notes that claim 1 now recites the subject matter of dependent claim 16, and dependent claim 16 is not addressed in the outstanding Office Action. Therefore, Applicant will address this rejection under the combination above and in view of the alleged disclosure in U.S. Patent No. 3,776,230 to Neeffe of a mold to reshape the cornea. The Neeffe patent is used to reject independent claim 31, which also recites placing a contact lens having a predetermined curvature on the surface of the cornea.

The Bille et al. patent discloses internally ablating a portion of the cornea, to form a region 52. The Simon patent teaches inserting a gel 34 into an annular chamber 30 in the cornea. Clearly, neither of these patents alone or in combination teaches using a contact lens having a predetermined curvature. Therefore, Applicant submits that amended independent claim 1 is allowable over the combination of the Bille et al. and Simon patents.

Moreover, the Neeffe patent does not overcome the deficiencies of these two references. The Office Action, in the rejection of the claim 31, alleges that the Neeffe patent teaches using a mold to reshape the cornea. In support of this rejection, the Action alleges that it would have been obvious to employ a mold to the combination of the Bille et al. and the Simon patents, since it would be more precise and less cumbersome than the manual massage disclosed in the Simon patent.

However, none of the cited patents actually discloses, teaches or suggests using a contact lens to reshape ocular material that is inserted under the cornea or provides motivation to do so. Specifically, the Neefe patent discloses molding the exterior surface of the cornea, it does not disclose, teach or suggest reshaping ocular material under the surface of the cornea. Merely because the Action states the benefit that the present invention may result in a procedure that is less cumbersome than the manual massage disclosed in the Simon patent, does not mean that the invention would have been obvious in view of the Bille et al., Simon and Neefe patents. The Examiner is using the benefits of the present invention as motivation to combine these references, and not any motivation or suggestion taught or disclosed in the prior art. Therefore, Applicant submits that the Examiner is using improper hindsight.

Furthermore, Applicant submits that prior art must teach or suggest every element recited in the claims. See MPEP §2143.03. There is no reference or combination that actually discloses, teaches or suggests using a contact lens to reshape an intracorneal material.

Therefore, Applicant submits that amended independent claim 1, and its respective dependent claims 2-15 and 17-19 are allowable over the cited prior art.

Claims 5, 6, 14, 15 and 20-23 stand rejected under 35 U.S.C. §103(a) over the Bille et al. patent in combination with the Simon patent and further in view of U.S. Patent No. 4,665,913 to L'Esperance, Jr.

With regard to dependent claims 5, 6, 14 and 15 Applicant submits that each of these claims are allowable for the reasons stated above, since they are dependent upon independent claim 1. Moreover, each dependent claim recites additional elements that further distinguish

them from the prior art. For example, claim 6 recites firing a second laser at a portion of the cornea overlying and located at the main optical axis. This is clearly not disclosed in the prior art.

Independent claim 20

The Action alleges that the Bille et al. and the Simon patents are applied as noted above, and the L'Esperance patent teaches using an excimer laser to ablate the external surface of the cornea. In support of the rejection, the Action alleges that it would have been obvious to be used to "fine tissue" the correction produced by the implant.

However, the Applicant submits that there is no single reference or combination of references that discloses, teaches or suggest a method recited in amended independent claim 20, including separating the internal area of the cornea offset from the main optical axis into first and second substantially ring-shaped internal surfaces to form a corneal pocket and using a laser to ablate a portion of the cornea *overlying the portion* of the first surface that remains attached to the second surface by the area *located at the main optical axis*.

By forming a pocket offset from the main optical axis, this portion of the eye (i.e., along the main optical axis) is not disturbed and therefore there is less likelihood that the healing of the cornea will result in halos or other vision impairments. Furthermore, by ablating the cornea on the external surface overlying this portion of the cornea, the vision of the patient can be "fine tuned" and corrected to better than 20/20 vision.

There is no combination of references that discloses, teaches or renders obvious this specific method. At best, the prior art teaches inserting a material under the surface of the cornea

in one instance, and ablating the entire surface of the cornea to reduce a myopic or hyperopic condition in another. There is no motivation in any of the cited references to combine the cited references to render obvious amended independent claim 20. The motivation used in the Action (i.e., to "fine tune" the correction produced by the implant) is motivation taught in the present invention. The motivation must come from the cited prior art or information that one of ordinary skill would possess. See MPEP §2143.01. Since there is no disclosure or teaching in the prior art of "fine tuning" a corrective procedure in this manner, the motivation used in this rejection is improper hindsight, and therefore the rejection cannot stand.

Furthermore, there is no disclosure or teaching in the prior art of forming a pocket offset from the main optical axis and ablating a portion of the cornea overlying the main optical axis.

Thus, Applicant submits that claim 20 and its respective dependent claims 21 and 23 are allowable.

Claims 24-30 stand rejected under 35 U.S.C. §103(a) as being unpatentable over the Bille et al. patent in combination with the Simon and the L'Esperance patents.

Independent Claim 24

Amended independent claim 24 recites subject matter that is substantially similar to amended claim 20. Specifically, claim 24 recites separating the internal area of the cornea offset from the main optical axis and ablating a portion of the cornea overlying the main optical axis, therefore independent claim 24, and its respective dependent claim 25-30 are allowable for the reasons stated above.

Claims 31, 34 and 35 stand rejected under 35 U.S.C. §103(a) as being unpatentable over the Bille et al. patent in combination with the Simon and Neeffe patents.

Additionally, dependent claims 32 and 33 are rejected under 35 U.S.C. §103(a) as being unpatentable over the Bille et al. patent in combination with the Simon and Neeffe patent and further in view of the L'Esperance patent.

Independent Claim 31

Independent claim 31 recites subject matter that is substantially similar to amended independent claim 1. Specifically, claim 31 recites placing a contact lens having a predetermined curvature on the surface of the cornea to shape an ocular gel, therefore independent claim 31, and its respective dependent claim 32-35 are allowable for the reasons stated above.


Additionally, with regard to the rejection of dependent claim 32 and 33, these claims are allowable since they are dependent from claim 31. Furthermore, the L'Esperance patent does not overcome the deficiencies of the Bille et al., the Simon and the Neeffe patents.

* * *

In view of the foregoing, claims 1-15, 17-21 and 23-35 are allowable. Prompt and favorable action is solicited.

Attached hereto is a marked-up version of the changes made to the claims and specification by the current amendments. The attached pages are captioned "**Version With Markings To Show Changes Made**".

Respectfully submitted,



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Version With Markings To Show Changes Made

IN THE CLAIMS:

Please cancel claims 16 and 22.

Please amend claims 1, 20 and 24-31 as follows:

1. (Amended) A method of modifying a cornea of an eye, the cornea having an external surface, an internal portion and a main optical axis, the method comprising the steps of

aiming a first laser at the internal portion of the cornea, adjacent the external surface,
firing the first laser at the cornea, which separates the internal portion of the cornea forming a first internal surface and a second internal surface, the first internal surface facing in a posterior direction of the cornea and the second internal surface facing in an anterior direction of the cornea, the first and second internal surfaces forming an internal pocket therebetween,

forming an opening from the external surface of the cornea to the internal pocket, [and]
introducing ocular material through the opening and into the internal pocket of the cornea; and

placing a contact lens having a predetermined curvature on the external surface of the cornea to shape the ocular material.

20. (Amended) A method of modifying a cornea of an eye having a main optical axis and an external surface, comprising the steps of

aiming an ultrashort pulse laser at the cornea,
firing the ultrashort pulse laser at the cornea, the laser separating the internal area of the cornea offset from the main optical axis into first and second substantially ring-shaped internal

surfaces to form a corneal pocket, a portion of the first internal surface remaining attached to the second internal surface by an area located at the main optical axis, the first internal surface facing in a posterior direction of the cornea and the second internal surface facing in an anterior direction of the cornea,

forming an opening from the external surface of the cornea to the internal pocket, and introducing an ocular material through the opening and into the internal pocket of the cornea, so that the ocular material at least partially encircles the portion of the first surface that remains attached to the second surface by the area located at the main optical axis,

aiming a second laser at the cornea, and

firing the second laser at an external surface of the cornea to ablate a portion of the external surface of the cornea overlying the portion of the first surface that remains attached to the second surface by the area located at the main optical axis.

24. (Amended) A [system] kit for corrective surgery of a cornea of an eye having a main optical axis, the combination comprising:

an ultrashort pulse laser adapted to separate an internal area of the cornea offset from the main optical axis into first and second internal surfaces to form a corneal pocket;

an ocular material adapted to be inserted in an opening into the corneal pocket and in-between the first and second internal surfaces of the corneal pocket; and

a second laser adapted to ablate a portion of a surface of the cornea overlying the main optical axis after said ocular material is inserted in-between the first and second internal surfaces of the corneal flap.

25. (Amended) A [system] kit according to claim 24, wherein

a portion of said first surface remains attached to said second surface by an area located at said main optical axis.

26. (Amended) A [system] kit according to claim 25, wherein

said ocular material is a substantially ring-shaped ocular material and is adapted to be inserted so that said ocular material at least partially encircles said portion of said first surface that remains attached to said second surface by said area located at said main optical axis.

27. (Amended) A [system] kit according to claim 26, wherein

said second laser is adapted to ablate a surface of the cornea at an area that overlies said portion of said first surface that remains attached to said second surface by the area located at said main optical axis.

28. (Amended) A [system] kit according to claim 24, wherein

said ocular material includes at least a first material which, when exposed to a first energy, is adapted to increase a volume of at least a portion of the ocular material substantially without ablation, and a second material which, when exposed to a second energy, is adapted to decrease a volume of at least a portion of the ocular material substantially without ablation.

29. (Amended) A [system] kit according to claim 24, wherein

said ultrashort pulse laser is a laser selected from the group consisting of a femtosecond laser, a picosecond laser and an attosecond laser.

30. (Amended) A [system] kit according to claim 24, wherein

said second laser is an excimer laser.

31. (Amended) A method of modifying a cornea having a main optical axis and an external surface, comprising the steps of

aiming and firing an ultrashort pulse laser at the cornea, which separates an internal area of the cornea adjacent the external surface into first and second internal surfaces to form an internal pocket, the first internal surface facing in a posterior direction of the cornea and the second internal surface facing in an anterior direction of the cornea,

forming an opening from the surface of cornea to the internal pocket,

introducing an ocular gel through the opening and into the internal pocket and in between the first and second internal surfaces of the internal pocket,

placing a contact lens having a predetermined curvature on the surface of the cornea to shape [he] the ocular gel, and

irradiating the ocular gel so that the ocular gel solidifies.